



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 3, 2017

Dr. Matthew Brooks
Regulatory Consultant
Cupron Inc.
c/o Ag-Chem Consulting
12208 Quinque Lane
Clifton, VA 20124

Subject: Notification per PRN 98-10 – Correction of typographical errors to the label
Product Name: Antimicrobial Cupron Enhanced EOS Surface
EPA Registration Number: 84542-7
Application Date: 04/04/2017
Decision Number: 528517

Dear Dr. Brooks:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you have any questions, you may contact Farzana Olla at 703-347-0190 or via email at olla.farzana@epa.gov.

Sincerely,

A handwritten signature in cursive script, reading "Fargana Olla". The signature is written in a dark ink and is positioned above the typed name and title.

for

Stacey Grigsby, Acting Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Master Label containing

Sublabel 1. Complete Label

Sublabel 2. Hang Tag label

Sublabel I. Complete Label

Antimicrobial Cupron Enhanced EOS Surface

Ingredients	
Copper (I) Oxide	16.0%
Other Ingredients	84.0 %
Total	100 %

EPA Registration No. 84542-7

EPA Establishment No

Net Contents*****

Manufactured by

Cupron Inc.
800 East Leigh St
Richmond VA 23219

NOTIFICATION

84542-7

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

05/03/2017

Label may contain 1 or more of the statements listed below in []

Antimicrobial Cupron Enhanced EOS Surface

Laboratory testing has shown that when cleaned regularly:

[This surface continuously reduces bacterial* contamination, achieving 99.9% reduction within two hours of exposure.]

[This surface kills greater than 99.9% of Gram negative and Gram-positive bacteria* within two hours of exposure.]

[This surface kills greater than 99.9% of bacteria* within two hours and continues to kill 99% of bacteria* even after repeated contamination.]

[This surface helps inhibit the buildup and growth of bacteria* within two hours of exposure between routine cleaning and sanitizing steps.]

*Testing demonstrates effective antibacterial activity against *Staphylococcus aureus* (ATCC 6538), *Enterobacter aerogenes* (ATCC 13048), Methicillin-Resistant *Staphylococcus aureus* (MRSA, ATCC 33592), *Escherichia coli* 0157:H7 (ATCC 35150), and *Pseudomonas aeruginosa* (ATCC 15442).

The use of an Antimicrobial Cupron Enhanced EOS Surface is a supplement to and not a substitute for standard infection control practices; users must continue to follow all current infection control practices, including those practices related to cleaning and disinfection of environmental surfaces. The Antimicrobial Cupron Enhanced EOS Surface has been shown to reduce microbial contamination but it does not prevent cross contamination.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[The directions in bracketed text may be included in an insert. If so there will be a statement to see the insert for additional directions for use of the product]

Proper Care and Use of Antimicrobial Cupron Enhanced EOS Surfaces:

The use of Antimicrobial Cupron Enhanced EOS Surfaces does not replace standard infection control procedures and good hygienic practices. Antimicrobial Cupron Enhanced EOS Surfaces must be cleaned and sanitized according to standard practice. Health care facilities must maintain the product in accordance with infection control guidelines; users must continue to follow all current infection control practices, including those practices related to disinfection of environmental surfaces.

Antimicrobial Cupron Enhanced EOS Surfaces may be subject to recontamination and the level of active bacteria at any particular time will depend on the frequency and timing of recontamination and cleanliness of the surface (among other factors). In order for the antimicrobial Cupron Enhanced EOS Surface to have proper antimicrobial effect, the product must be cleaned and maintained according to the directions included on this label.

This product must not be waxed, painted, lacquered, varnished, or otherwise coated.

Routine cleaning to remove dirt and filth is necessary for good sanitation and to assure the effective antibacterial performance of the Antimicrobial Cupron Enhanced EOS Surface. Cleaning agents typically used for traditional touching surfaces are permissible; the appropriate cleaning agent depends on the type of soiling and the measure of sanitization required. [Normal tarnishing or wear of the Antimicrobial Cupron Enhanced EOS Surface will not impair the antibacterial effectiveness of the product].

This product must not be used on any direct food contact or food packaging uses.

[Antimicrobial Cupron Enhanced EOS Surfaces may be used in hospitals, other healthcare facilities, and various public, commercial and residential buildings for the non-food contact surfaces listed below.]

[The following statement will appear on the label if the use involves potential exposure to outdoor conditions: Surfaces that may be exposed to outdoor environmental conditions (e.g., handrails, shopping carts, child seats and ATM machines) are not representative of indoor laboratory conditions, and therefore, may impart reduced efficacy if not cleaned when visibly soiled.]

Healthcare Facilities

- Bedrails, footboards
- Over-bed tables
- Bed Side tables in hospitals, extended care facilities, senior housing etc. (knobs, pulls, handles; surfaces)
- Handrails (corridor/hallways) (Senior Housing), automatic door push plates
- Stair treads, Stair rails, handrails, tubular railing, and supports, rail fittings T's, elbows and brackets
- Bedrails, assistance rails
- Toilet Safety rails
- Carts
 - Hospital carts (table surfaces, handles, legs)
 - Computer carts
 - Record carts
 - Phlebotomy carts
 - Other Carts (tables/surfaces, shelving, railings, handles, pulls)
- Equipment carts (horizontal surfaces, frames, handles)
- Doors, Door push plates, kick plates, mop plates, stretcher plates
- Sinks , drains, one piece sinks
- Paper towel holders, facial tissue holders, toilet paper holders
- Hydrotherapy tanks (whirlpool tanks): shells, covers, headrests, drain fittings (outer surfaces without water contact)
- Door handles, doorknobs (outer touch surface)
- Panic bars on emergency room doors
- Towel bars
- Countertops and tabletops (non-food contact surface use only)
- Door stops, door pulls and protector guards
- Light switches, switch plates
- Kitchen surfaces (non food contact surfaces only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, controls knobs (appliances, fans)
- Floor tiles
- Ceiling tiles
- Wall decorative tiles
- Instrument casing and molded knobs, pulls and handles
 - Medical equipment knobs, pulls and handles for
 - Drug delivery systems
 - Monitoring systems
 - Hospital beds
 - Office equipment

- Operating room equipment
- Stands and fixtures

Types of knobs-e.g. Prong, fluted, knurled, push/pull, T handle, tapered and ball knobs

- Trays (instruments, non food contact only)
- Physical therapy equipment: physical therapy tables, treatment chairs and portable taping tables
- Chairs frame or chair hard surface (shower chairs, patient chairs, visitor chairs): rails, backs, legs, seats
- Headwall systems: the unit themselves, outlet covers, monitor housings, knobs, baskets, tables
- Critical care cart: Table top, drawer
- Toilet seat, toilet seat cover, door and cabinet facings, counter tops
- Storage Shelving: wire shelving etc for medical supplies
- Grab handles on privacy curtains
- laundry hampers, trash canisters, and other containers
- Window sills,
- Electrical wall plates

Community Facilities (including various public and commercial buildings):

- Shopping carts, child seats, handrails
- Gym/Health club lockers, locker handles, locker shelving, trainers' tables,
- Elevator: handrail, control panels, interior walls, floor tiles, exterior call button plate
- Toilet paper dispenser (housing)
- Windows (crank)
- Light switches, switch plates
- laundry hampers, trash canisters, and other containers
- Window sills
- Electrical wall plates

Residential Buildings (including homes, apartments, apartment buildings and other residences:-

- Kitchen surfaces (non-food contact only): table tops, counter tops, handles (microwave, refrigerator, stove), cabinet doors, cabinet hinges, pulls, backsplash, hoods, control knobs (appliances, fans)
- Bedrails, footboards
- Handrails, stair treads, stair rails
- Stair rails
- Door push plates, doors
- Sinks, drains, sinks themselves
- Door handles, doorknobs (outer touch surfaces)
- Towel bars
- Countertops and tabletops
- Light switches, switch plates

- Floor tiles
- Ceiling tiles
- Wall decorative tiles
- Exercise and gym equipment, handles, bars
- laundry hampers, trash canisters, and other containers
- Window sills
- Electrical wall plates

Mass Transit Facilities

- Wall panels
- Handrails
- Stair rails, stair treads, railing and supports; elbows and brackets
- Door push plate, kick plates
- Door handles, door knobs (outer touch surfaces)
- Grab bars and handles
- Tiles: wall, floor, ceiling (non-porous)
- Chairs and benches: rails, backs, legs, seats
- Window sills, pulls, and handles

STORAGE AND DISPOSAL

ANTIMICROBIAL CUPRON ENHANCED EOS SURFACES should be disposed of in a responsible manner, including recycling.

WARRANTY STATEMENT

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Tree injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or tree conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of CUPRON INC. or seller. To the extent consistent with applicable law, all such risks shall be assumed by Buyer and User, and Buyer and User agree to hold CUPRON INC. and seller harmless for any claims relating to such factors.

CUPRON INC. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions. This warranty does not extend to the use of the product contrary to label instructions, and Buyer and User assume the risk of any such use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, CUPRON INC. MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

Sublabel 2. Hang Tag

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